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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/801,471

03/08/2001

Leon W.M.M. Terstappen

Immunivest

4953

7590 01/03/2007  
IMMUNICON CORPORATION  
3401 MASONS MILL ROAD  
SUITE 100  
HUNTINGDON VALLEY, PA 19006

EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/801,471	TERSTAPPEN ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-4, 7-14, 16-23, 27-31, 34-42, 46 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4, 7-14, 16-23, 27-31, 34-42, 46 and 55-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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### **DETAILED ACTION**

Claims 1-4, 6-14, 16-23, 27-31, 33-42, 46-50 and 54 are pending and under consideration. The finality of the Office action of March 11, 2003 is withdrawn in light of the new grounds of rejection below.

Claim 6, 33, 47-50 and 54 have been canceled. Claims 1, 7, 9, 10, 11, 16, 17, 20-22, 28-31, 34-37, 39, 40, 41, 42 and 46 have been amended. Claims 55-59 have been added. Claims 1-4, 7-14, 16-23, 27-31, 34-42, 46 and 55-59 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

Applicant is reminded that the priority date of the instant application is March 7, 2001.

Claims 1-4, 10-14, 28-31, 35-42, 46, 55-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites an "improved kit" but fails to recite to what the improvement is in reference to.

Claims 1, 10, 28 recite "efficient immunomagnetic recovery". The term "efficient" is a relative term which renders the claim indefinite. The term "efficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

Claims 1-4, 7-14, 16-23, 27-31, 34-42, 46 and 55-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 7, 10, 20, 37 have been amended to recite the limitation "wherein said spectra are detected through the same spectral window"..

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The specification teaches that  
*Labeling two different cellular components also allows facile dual labeling of control cells with two structurally and spectrally different fluorophores.*

This fails to provide support for the instant amendment requiring different emission spectra which are detected through the same spectral window because no mention is made of spectral windows in the disclosure.

Claim 28 has been amended to recite “wherein said stability provides efficient immunomagnetic recovery in rare cell analysis”. Claim 1 has been amended to recite “wherein said physical and biological stability provides efficient immunomagnetic recovery in rare cell analysis”. The originally filed disclosure fails to provide support for this amendment wherein specifically the stability of the control cell, per se, is the basis of enhanced immunomagnetic recovery.

Claim 16 has been amended to recite “wherein said stabilization does not alter light scattering and autofluorescent properties of the detectable label on the control cell. The originally filed disclosure does not provide specific support for preserving light scattering and autofluorescent properties.

Claim 35 and 55 recite the limitation of “cellular components and antigenic moieties of said control cells have been stabilized for at least six months”. The originally filed disclosure contemplates the control cell having a stability of up to six months and does not provide support for the instant new claim which requires that the control cells be in the process of stabilization for six months before they are part of the kit. Amendment of the claim to read “the control cells are stable” rather than “the control cells have been stabilized” will overcome this rejection.

All other rejections and objections are withdrawn in light of applicants amendments.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

12/26/2006

  
KARENA CANELLA PH.D.  
PRIMARY EXAMINER